Remarks

I. Support for the Amendments

Of the 7 original claims, non-elected claims 2-7 have been canceled and claim 1 has been amended. Claim 8 has been added. Support for the foregoing claim amendments may be found throughout the specification and in the original claims, for example at page 9, line 24 through page 10, line 3 and page 19, line 9 through page 20, line 10. Upon entry of the foregoing amendments, claims 1 and 8 are pending in the application. The specification has been amended to remove the phrase "http://", embedded hyperlinks, and to correct typographical errors. No new matter enters by these amendments.

II. The Restriction Requirement

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully point out that the expressed USPTO policy, as set forth in the Manual of Patent Examining Procedure, states that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (MPEP, 8th ed., August 2001, Section 803.04, page 800-10). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.*

The Examiner has presented no evidence to support this departure from the articulated USPTO policy. However, in order to facilitate prosecution Applicants have removed non-elected sequences from the claims.

III. The Objection to the Specification

The Examiner objects to the disclosure at page 3 because it contains an embedded hyperlink and/or other forms of browser-executable code on pages 5 and 28 of the specification. According to MPEP § 608.01, embedded hyperlinks and browser executable code are not permitted. The specification has been amended to remove the phrase "http://", underlining, and embedded hyperlinks.

IV. Rejection under 35 U.S.C. § 101

Claim 1 was rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well established utility as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "comparative sequence analysis or to identify sequence motifs"; "to transform plants, to determine association with polymorphic sites, to determine a pattern or level of protein expression, to detect mutations, or to reduce protein expression"; and to obtain other nucleic acid sequences, to identify mutations and polymorphisms, to assist in genetic mapping, and as markers. Office Action at pages 4-5. However, despite this admission and numerous uses cited throughout the specification, the examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines.[1]

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[1] Applicants respectfully point out that the Patent Office has said the Interim Guidelines "do not constitute substantive rulemaking and hence do not have the force and effect of law. They are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable." Department of Commerce, Patent and Trademark Office, *Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112(1) 'Written Description' Requirement*, Fed. Reg. Vol. 63, No. 114 (June 15, 1998), page 32639. As such, the examiner's sole reliance on the Guidelines (Office Action at 4-7) is improper.

Applicants respectfully disagree. The application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecule is useful in determining the presence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, *etc.* (*see e.g.,* Specification, beginning at page 33, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating that these "are general utilities applicable to any polynucleotide sequence and are not specific to elected SEQ ID NO: 1." Office Action at page 4. *See also Id.* at page 5.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See*

Carl Zeiss Stiftung v. Renshaw PLC, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecule encompasses many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequence exhibits the requisite utility under 35 U.S.C. § 101.

Surprisingly, the Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 7. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir.

1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecule is supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

V. The Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

VI. Rejection of Claim 1 under 35 U.S.C. §112, 1st Paragraph: Written Description

Claim 1 was also rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

The Examiner does not contest that Applicants have disclosed SEQ ID NO: 1 and, as such, have *per se* met the written description provision of 35 U.S.C. § 112, first paragraph with respect to this sequence. However, the Examiner contends that the specification does not disclose "that any polypeptide sequence putatively encoded by SEQ ID NO: 1 MUST be a maize protein." Office Action at page 8. According to the Examiner, claim 1 lacks sufficient written description because "[t]he instant specification fails to teach that SEQ ID NO: 1 encodes any polypeptide, specifically a maize protein". *Id.* However, such an assertion is unfounded.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader that the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, simply because the claimed nucleic acid sequences may also include mutations, allelic variations, splice variations and the like, does not require that Applicants describe each and every one of these molecules.

Contrary to the Examiner's assertion, the specification discloses that SEQ ID NO: 1 belongs to the family of *zea mays* (see sequence listing). Furthermore, the Examiner has provided no evidence that a skilled artisan would not readily recognize that Applicants had possession of SEQ ID NO: 1 as of the filing date of the application. The fact that the nucleic acid molecules may comprise additional sequences, or variations, or may even encode non-maize proteins is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification.

The present claim "distinguish[es] the claimed invention from others" and defines "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA."). Thus, there is no deficiency in the written description support for the claimed invention.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

In view of the above, the presently pending claim is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Applicants do not believe that any fees are due at this time; however, should any fees be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Deposit Account No. 13-4125, referencing docket number 38-21(15503)B.

Respectfully submitted,

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Marked-Up Version of Amended Specification

At page 5, lines 16-23:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) [(http://www.ddbj.nig.ac.jp/)] (www-ddbj.nig.ac.jp/); Genebank [(http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html)] (www-ncbi.nlm.nih.gov/web/Genbank/Index.html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) [(http. www.edi.ac.uk/ebi_docs/embl_db.html)] (www-edi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequence queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology, 12:* 76-80 (1994); Birren, *et al., Genome Analysis, 1:* 543-559 (1997)).

At page 28, lines 1 to 8:

A PCR probe is a nucleic acid molecule capable of initiating a polymerase activity while in a double-stranded structure with another nucleic acid. Various methods for determining the structure of PCR probes and PCR techniques exist in the art. Computer generated searches using programs such as Primer3 [(www-genome.wi.mit.edu/cgi-bin/primer/primer3.cgi)] (www-genome.wi.mit.edu/cgi-bin/ primer/primer3.cgi), STSPipeline [(www-genome.wi.mit.edu/cgi-bin/www-STS_ Pipline)] (www-genome.wi.mit.edu/cgi-bin/www-STS_Pipline), or GeneUp (Pesole *et al., BioTechniques 25:*112-123 (1998) the entirety of which is herein incorporated by reference), for example, can be used to identify potential PCR primers.

Marked-Up Version of Amended Claims

1. (Once amended) A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 13524].

8. (Added) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1.